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8 UNITED STATES DISTRICT COURT
9 SOUTHERN DISTRICT OF CALIFORNIA
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11 MARIA FLORES, by and through her
12 guardian, Josie Clark,

13 Plaintiff,

14 v.

15 THE UNITED STATES OF AMERICA,

16 Defendant.
17

Case No.: 3:15-cv-00836-GPC-DHB

**FINDINGS OF FACT AND
CONCLUSIONS OF LAW
FOLLOWING BENCH TRIAL**

18 Maria Flores, by and through her guardian Josie Clark (“Plaintiff”), brings this
19 action against Defendant United States of America (“Defendant” or “the Government”)
20 for injuries sustained due to an “overdose” of rivastigmine, (also known as the “Exelon
21 Patch,” “the Patch,” or “Exelon”) a transdermal medication, that occurred at the San
22 Ysidro Health Center (“SYHC” or “the Center”) located in San Diego County. Pl.’s Trial
23 Brief, Dkt. No. 36 at 1-2. Plaintiff asserts that the nursing staff at SYHC committed
24 medical negligence when they applied an Exelon Patch to Flores without removing a
25 prior patch, thereby causing the “overdose.” *Id.* The Court held a bench trial on June 5-
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1 7, 2017.¹ Alvin M. Gomez appeared on behalf of Plaintiff and Steve B. Chu and Glen
2 Dorgan appeared on behalf of Defendant. Having carefully reviewed the evidence and
3 the arguments of the parties, as presented at trial, and in their written submissions, the
4 Court makes the following findings of fact and conclusions of law pursuant to Rule 52 of
5 the Federal Rules of Civil Procedure.

6 **FINDINGS OF FACT**

7 **A. The Parties**

8 The San Ysidro Health Center is an adult daycare center for patients who require
9 assistance with basic activities of daily living. The Center takes care of participants
10 Monday through Friday from approximately 8:00 am to 5:00 pm and, depending on
11 enrollment, can have up to one hundred individuals in attendance on a weekly basis.
12 SYHC employs a number of registered nurses, social workers, and other individuals who
13 together form a care team to watch over the Center's participants.

14 Maria Flores, born January 8, 1934, was living with her daughters, Josie Clark and
15 Leticia Reynoso ("daughters"), prior to her enrollment at San Ysidro Health Center.
16 Plaintiff moved in with her daughters, who alternated handling her care, in 2012 because
17 she could no longer take care of herself. She was experiencing memory problems and
18 would get confused easily. It was difficult for her to follow a conversation. While living
19 with her daughters, Flores began wandering out of the house, into the street. To prevent
20 any harm resulting from such behavior, the daughters placed deadbolts on their homes to
21 ensure their mother would not leave when she was not being watched over.

22 Sometime between the late summer and fall of 2013, the daughters decided to
23 enroll their mother in a caregiver program. They looked at three different centers before
24 deciding on SYHC. They settled on SYHC because it had Spanish-speaking staff, as
25 Plaintiff only spoke Spanish, had activities for the enrollees, and was close to Reynoso's
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28 ¹ 28 U.S.C. § 2402 states that actions brought against the United States of America under the Federal
Tort Claims Act shall be tried by the court without a jury.

1 place of work. Soon thereafter, Flores was accepted into the SYHC program. Flores
2 attended the program Monday through Friday for at least four hours per day. A bus went
3 to the homes of the daughters to retrieve Flores in the morning and afternoon, as she was
4 no longer driving in 2013.

5 **B. Flores' Medical Background**

6 Dr. Michael Lobatz, an expert in neurology, testified that the first mention of
7 Alzheimer's in Flores' medical records appeared on April 29, 2011. Flores had visited
8 her primary care physician, Dr. Sharna Shachar, with her son who told the doctor that his
9 mother had short-term memory loss, was sleeping more, was getting frustrated and
10 forgetful, and had become slightly paranoid and accusatory. Dr. Shachar diagnosed
11 Flores with dementia and prescribed her donepezil to ameliorate the symptoms.

12 About two years later, Flores saw Dr. Roberto Gratianne, a neurologist, on
13 February 18, 2013. Joint Exhibit 17-024. Dr. Gratianne's medical records indicate that
14 Flores presented herself to him for an evaluation of her memory loss. At that time, she
15 had a history of progressive dementia that had started back in 2008 and that had been
16 diagnosed in 2010. She required constant supervision and help with self-care. Dr.
17 Gratianne's contemporaneous records also indicate that Flores was exhibiting behavioral
18 problems as she thought her son was her husband. In fact and according to Dr. Lobatz,
19 Flores' primary care physician, Dr. Shachar, had prescribed Flores an antipsychiatric
20 tranquilizer, called risperdal, at around the time she began to see Dr. Gratianne.

21 Dr. Lobatz testified that Dr. Gratianne performed a standard cognitive evaluation
22 of Flores called the Mini Mental Status Examination ("MMSE"). The MMSE has a total
23 score of 30 points. Achieving 26 points or greater would be expected for a normally
24 educated individual. Twenty to 26 points would be indicative of mild cognitive changes
25 and 10 to 20 points would be indicative of moderate changes. Below 10 points indicates
26 a severe condition. The MMSE, however, does not test behavioral symptoms. Dr.
27 Lobatz testified that in individual with mild memory loss, but very bad behavior
28 associated with cognitive degeneration, would have a severe, not a mild case.

1 Flores scored a 13 out of 30 on the MMSE administered by Dr. Gratianne on
2 February 18, 2013. She scored a 12 out of 30 on the MMSE administered by Dr.
3 Gratianne on April 24, 2013. Dr. Lobatz testified that the results of the April
4 examination alone, and not including any behavioral symptoms, indicated that Flores had
5 significant moderate dementia approaching severe. A third MMSE was administered to
6 Flores by Dr. Gratianne in July 2013. She scored an 11 out of 30 on that test. According
7 to Dr. Lobatz, that the July score was similar to the April score validated the
8 abnormalities recorded by the April MMSE.

9 Dr. Gratianne diagnosed Flores with Alzheimer's at her February 2013
10 appointment. He subsequently examined her in April 2013, June 2013, July 2013,
11 August 2013, November 2013, and on January 4, 2014. According to Dr. Gratianne's
12 November 2013 records, Flores was not doing well. She had worsening balance, gait and
13 mental status. She was also having occasional hallucinations. According to Dr.
14 Gratianne's January 4, 2014 records, Flores arrived in a wheelchair and needed total
15 care and constant supervision at that time.

16 SYHC also assessed Flores at the time of her enrollment. Dr. Lobatz testified that
17 SYHC performed a somewhat similar test called the SLUMS (St. Louis University
18 Mental Status Examination). Dr. Lobatz testified that the SLUMS is more sensitive to
19 milder forms of early dementia, but that once an individual has more severe symptoms,
20 the SLUMS and MMSE start approaching one another in terms of their sensitivity. On
21 average, Dr. Lobatz testified, a SLUMS score is about 4.5 points less than a MMSE
22 score. Staff at SYHC performed a SLUMS on Flores on September 25, 2013. Joint
23 Exhibit 15-140. She scored 4 out of 30 points on the examination, which, Dr. Lobatz
24 testified, is roughly equivalent to a score of 8.5 on the MMSE.

25 Given her MMSE and SLUMS scores, Dr. Lobatz testified that as of September
26 2013, Flores was at the 8-to-10 level of the MMSE. Dr. Lobatz testified that in
27 September 2013 Flores' Alzheimer's disease was very severe.

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C. The Exelon Patch

On November 21, 2013, Dr. Roberto Gratianne prescribed Flores Exelon, or rivastigmine, at a dosage of 4.6 mg/24 hours to aid with her Alzheimer's symptoms. Joint Exhibit 7-001.² According to SYHC's records, Flores began taking Exelon on December 5, 2013. Joint Exhibit 4-002.

Dr. Lobatz testified that Exelon ameliorates Alzheimer's symptoms by enhancing short term memory. Acetylcholine is a neurotransmitter that is correlated with short term memory. The more acetylcholine present in the brain, the better one's memory. Dr. Lobatz testified that as acetylcholine levels drop in Alzheimer's disease, memory worsens gradually. Accordingly, Dr. Lobatz testified, one strategy for treating Alzheimer's disease is to prescribe a medication that increases the acetylcholine level within the brain. Acetylcholine is broken down by an enzyme that naturally occurs in the brain called cholinesterase. As such, to increase acetylcholine levels to help memory, doctors prescribe cholinesterase inhibitors, which prevent the acetyl cholinesterase enzyme from breaking down acetylcholine. Rivastigmine is a cholinesterase inhibitor. The drug was first developed as an oral medication and later developed as a transdermal patch.

Dr. Lobatz testified that the Exelon Patch is dosed initially at 4.6 mg per 24 hours. When an Alzheimer patient begins therapy, he or she starts at the lowest possible dose, which is 4.6 mg per 24 hours. If the individual is tolerating the medication, the effective dose is increased to 9.5 mg per 24 hours. Dr. Lobatz testified that there was nothing in Flores' medical records prior to January 7, 2014 to indicate that Flores was not tolerating the medication.

² The Court observes that Dr. Roberto Gratianne's records indicate that Flores did not begin taking Exelon until her next visit, January 3, 2014. Flores' script for Exelon, however, as obtained from CVS pharmacy, leaves little doubt that Dr. Gratianne had prescribed Flores Exelon on November 23, 2013, the same date as her November appointment with Dr. Gratianne. *See* Joint Exhibit 7. Regardless, this inconsistency is of little consequence as no party disputes that Flores was taking Exelon at the time of the incident pursuant to a valid prescription.

1 Dr. Richard Clark, an expert in toxicology, testified that the Exelon Patch is similar
2 to a small Band-Aid that has a reservoir of the drug impregnated within it. The drug
3 diffuses into the skin surface and then into the fat level right below the skin. As the drug
4 diffuses into the fat, it is slowly absorbed by the blood vessels travelling through the skin,
5 which then distribute the drug throughout the body. The Patch dispenses the drug
6 throughout the 24 hours that it is applied.

7 **D. Date of Incident**

8 SYHC's medical records indicate that, as of January 7, 2014, Flores was taking
9 two oral medications per day: Namenda for her dementia and Citalopram, an
10 antidepressant. Those records also indicate that Flores was contemporaneously receiving
11 rivastigmine through the Exelon Patch once per day. SYHC was responsible for applying
12 the Patch and administering her other medications, Monday through Friday. Over the
13 weekends, the daughters would administer their mother's medication, including the
14 transdermal Exelon Patch.

15 On Tuesday, January 7, 2014, Flores arrived at the Center. Flores used a walker at
16 the Center to assist her with ambulating. Registered nurses Alejandro Florez, Shirley
17 Roman, and Claudia Gonzalez were all present at SYHC that morning. Absent from the
18 roster was Yessica Toscano, the individual who dispenses medication to the Center's
19 participants on a daily basis. Because Toscano was not working that day, the other floor
20 nurses, Florez, Roman, and Gonzalez, were responsible for performing Toscano's duties.
21 According to Flores' Medication Administration Record, Flores received the Exelon
22 Patch at 10:00 am each morning. Joint Exhibit 15-074.

23 The floor nurses had trouble locating the bottle containing Flores' Citalopram
24 medication on the morning of January 7, 2014. As a result, Gonzalez called Clark at
25 10:21 am to report that staff could not find Flores' medication and that the daughters
26 needed to bring some. Joint Trial Exhibit 19-001. A few minutes afterwards, at
27 10:28 am, Clark called Reynoso, her sister, about the missing medication.
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1 Following the report about Flores' medication, Reynoso headed to the Center and
2 arrived late morning, before noon. Reynoso recalls that she arrived at the Center before
3 noon because she was late to go on a lunch date with her husband, which they had
4 scheduled around noon. When she arrived at the facility, the staff told her that they had
5 already found Flores' medication and already administered it to her.³ While at the
6 Center, Reynoso observed that her mom was "restrained" in a seated position and that she
7 did not have her walker. Seeing her mother in this state upset Reynoso. She found
8 another walker somewhere in the facility, unbuckled her mom, and watched her for a
9 while. Sometime thereafter she left to have lunch with her husband at IHOP.

10 Roman had administered Flores' medication that day. Roman first gave Flores her
11 Namenda. Next, she turned to Flores' transdermal medication. Roman consulted Flores'
12 Medical Administrative Record, Joint Exhibit 15-074, to determine where Gonzalez had
13 administered Flores' Exelon Patch the previous day. As Roman tried to administer the
14 medication to Flores' back, Flores tried to hit Roman with her elbows. She had become
15 agitated after taking the Namenda. Roman did not visualize Flores' skin before removing
16 and placing the new Exelon Patch. Instead, she used her hands to feel for the previous
17 day's patch. Roman testified that she removed a patch from Flores' right upper back.
18 She placed the old patch on her glove and noticed that there was a long white hair on it.
19 She testified that she specifically recalls removing a patch because she felt bad because
20 she thought she had pulled a hair from Flores' head.

21 Roman testified at her deposition that she administered Flores her medications
22 soon after 11:00 am. At trial, however, Roman testified that she gave Flores her
23 medication closer to 1:00 pm than 12:00 pm. She stated that only fifteen or so minutes
24 had passed between the time that she administered Flores her medication and the time
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27 ³ Although staff told Reynoso that they had found her missing Citalopram and that they had already
28 given Flores "her medication," the record is clear that Flores never took Citalopram on the morning of
January 7, 2014.

1 that Flores began vomiting, which was between 1:00 pm and 1:15 pm, approximately.
2 Roman states that she recalls that the vomiting began fifteen minutes after she
3 administered Flores' medication because she had specifically thought that Flores must
4 have been throwing up the oral medication. The Court, however, finds that Roman's
5 deposition testimony is more credible than her trial testimony given that it was taken
6 closer in time to the incident — that is, on February 19, 2016, more than fifteen months
7 prior to her trial testimony — and because it coincides with the testimony provided by
8 Reynoso, which indicated that Flores had received her medication prior to noon.
9 Accordingly, the Court finds that Flores received her prescribed dose of Exelon at
10 approximately 11:00 am.

11 Sometime thereafter, at around 1:00 pm, Flores became nauseous and began to
12 vomit. Before 1:00 pm, Gonzalez had noticed that Flores appeared pale, cold, and
13 clammy. Around 1:00 pm, Gonzalez realized that Flores was not well. Gonzalez
14 observed Flores sitting in a chair with vomit in her lap. Gonzalez instructed a Certified
15 Nursing Assistant (CNA) to get the vital machine to check Flores. Once the CNA
16 returned with the vital machine, Gonzalez began to measure her signs. Gonzalez
17 observed that Flores was conscious but that she had begun to slouch on the side of her
18 chair. She noticed that Flores was sweating and that she had stopped vomiting. When
19 Gonzalez could not pick up a pulse anymore, she asked the CNA to call "Code Blue."

20 According to the Comprehensive Report of the Paramedics, they received a call at
21 1:20 pm for a patient in cardiac arrest and they arrived at 1:23 pm. Joint Exhibit 9. Upon
22 arrival at the Center, the paramedics found Flores laying on the floor on her back. The
23 paramedics reported that Flores was nonresponsive, cold, pale and dry. Flores was PEA,
24 meaning she had pulseless electrical activity. She was also suffering from bradycardia, a
25 slow heart rate, as her heart was beating at 30 bpm (beats per minute). The paramedics
26 proceeded to perform CPR. Flores remained PEA until she was intubated. Dr. Barnard
27 testified that Flores had, indeed, experienced cardiac arrest given that she required
28 resuscitation to regain her vital signs.

1 Once Flores was intubated, her heart rate increased from 30 bpm to 132 bpm. The
2 patient remained intubated and unresponsive en route to the hospital. Both of Flores'
3 daughters, along with Flores' granddaughter Yolanda Clark, were onsite while the
4 paramedics were present. They had arrived after 9-1-1 was called. Josie Clark testified
5 that when she arrived at the Center she observed vomit everywhere and that her mother
6 was on her back.

7 Flores was taken to Sharp Chula Vista Hospital for treatment. Joint Exhibit 13-259
8 – 13-511. While at the hospital and after discussing Flores' DNR (Do Not Resuscitate)
9 status, the daughters decided to remove their mother's breathing tube, believing that she
10 would die. Joint Exhibit 13-260. Flores' other children were present at her bedside
11 because the daughters had called to inform them of their mother's state. Hospital staff
12 removed Flores' breathing tubes. Flores started gasping and made an unexpected
13 recovery. Dr. Robert Clark, the Government's expert in toxicology, reviewed the
14 hospital records and testified that Flores improved while in the emergency room. She
15 remained in the hospital for two nights. She was discharged on January 9, 2014.

16 **E. Flores' State Post-January 7, 2014**

17 The daughters testified as to Flores' affect and physical condition post-January 7,
18 2014. Josie Clark testified that her mother was not speaking at the hospital on January 8,
19 2014 and that she was non-responsive. She also testified that she noticed markings and
20 bruises on her mother's body while she was still in in-patient care. Joint Exhibit 22-005,
21 22-006. Clark went on to testify that after the incident, Flores could not walk anymore,
22 that she could not feed herself, that she could not get dressed on her own, and that she
23 had to wear diapers. She testified that Flores no longer spoke to her daughters and that
24 when she did, she did not make any sense. According to Clark, after the incident, Flores
25 was no longer affectionate, lacked emotion, and no longer recognized individuals she
26 once knew. Leticia Reynoso, Flores' other daughter, testified that Flores needed 24/7
27 care after the incident. She observed, like her sister, that Flores could no longer
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1 communicate after the event, that she could no longer walk on her own, and that she
2 could not do certain activities, like puzzles, anymore.

3 Plaintiff's primary physician, Dr. Shachar, also had the opportunity to evaluate
4 Flores post-January 7, 2014. On January 17, 2014, just ten days after the incident, Flores
5 presented herself to Dr. Shachar to be evaluated post-hospitalization, and at that time Dr.
6 Shachar recorded that Flores was "back to baseline." Joint Exhibit 16-187.

7 CONCLUSIONS OF LAW

8 The Federal Tort Claim Act makes the federal government liable to the same
9 extent as private individuals under like circumstances in accordance with California law.
10 28 U.S.C. §§ 1346(b)(1); 2674.

11 Plaintiff has sued the United States of America for medical negligence.
12 "Negligence" is the failure to exercise the care that a reasonable person would under the
13 circumstances. *Massey v. Mercy Med. Ctr. Redding*, 180 Cal. App. 4th 690, 694 (2009)
14 (citing *Delaney v. Baker*, 20 Cal. 4th 23, 31 (1999)). Medical negligence is a type of
15 negligence and general principles of negligence apply. *Id.* Accordingly, to establish
16 negligence, Plaintiff must demonstrate the (1) existence of a legal duty of care; (2) breach
17 of that duty; (3) and proximate cause resulting in injury. *Castellon v. U.S. Bancorp*, 220
18 Cal. App. 4th 994, 998 (2013) (citing *Ladd v. Cnty. of San Mateo*, 12 Cal. 4th 913, 917-
19 18 (1996)). Here, Plaintiff is alleging that the nursing staff at San Ysidro Health Center
20 committed medical negligence when they failed to remove the old Exelon Patch before
21 placing a new patch. Pl.'s Trial Brief, Dkt. No. 36 at 2.

22 **A. Standard of Care**

23 A nurse is negligent if he or she fails to meet the standard of care, "that is, fails to
24 use the level of skill, knowledge, and care that a reasonably prudent nurse would use in
25 similar circumstances." *Massey*, 180 Cal. App. 4th at 694. "The standard of care against
26 which the acts of a medical practitioner are to be measured is a matter peculiarly within
27 the knowledge of experts; it presents the basic issue in a malpractice action and can only
28 be proved by their testimony, unless the conduct required by the particular circumstances

1 is within the common knowledge of laymen.” *Alef v. Alta Bates Hosp.*, 5 Cal. App. 4th
2 208, 215 (1992). A nurse’s conduct must be measured by that of other nurses in the same
3 or similar locality and under similar circumstances, not by the standard of care required
4 by a physician or surgeon. *Id.* The standard of care is the minimal level of care to which
5 a patient is entitled. *Id.*

6 Both nursing experts testified that it would be below the standard of care for a
7 nurse to apply an Exelon Patch without removing a previous transdermal patch. Daniel
8 Marinelli, Plaintiff’s expert in nursing, testified that the failure to remove a previous
9 Exelon transdermal patch, prior to administration of a new patch, falls below the standard
10 of care regardless of who applied the previous patch. Constance Paine, the Government’s
11 expert nurse, similarly testified that the standard of care requires nurses to ensure that
12 there is only one Exelon Patch on a person at any time. Accordingly, the Court concludes
13 that the standard of care requires that a nurse ensure that there is only one Exelon Patch
14 on a patient at a time.

15 **B. Breach**

16 Roman was responsible for dispensing medication to Flores on January 7, 2014.
17 She was the last person to place an Exelon Patch on Flores before she was brought to the
18 hospital. Roman testified that she did not visualize Flores’ skin before placing a patch on
19 Flores’ back on the day of the incident. After Flores was brought to the hospital, two
20 Exelon Patches were found on her person. Roman testified that she learned after the fact
21 that hospital personnel had found two patches on Flores.

22 The Court concludes that this evidence is sufficient to establish a breach of the
23 standard of care. There is no dispute that two Exelon Patches were found on Flores’
24 person while at Sharp Chula Vista Medical Center. There is also no dispute that Roman
25 was the last person to apply an Exelon Patch to Flores. Roman’s conduct fell below the
26 standard of care because she failed to ensure that Flores had only one patch placed on her
27 person, regardless of the origins of the other Exelon Patch that Roman did not place.
28 After dispensing Flores’ medication on January 7, 2014, Flores had two patches on her

1 person. Accordingly, Roman breached the standard of care. The Court moreover notes
2 that this conclusion does not depend on whether the Court credit's Roman's testimony
3 that she did, in fact, remove an Exelon Patch before placing a new one. At the end of the
4 day, two patches were found on Flores' person and Roman was the person responsible for
5 ensuring she only had one Patch placed on her person. As such and given that the
6 standard of care, as articulated by both experts, requires a nurse to ensure there is only
7 one Patch on a person at a time, Plaintiff has demonstrated breach of the standard of care.

8 **C. Cause in Fact**

9 Plaintiff must demonstrate that it is more likely than not (i.e., by a preponderance
10 of the evidence) that Defendant's conduct was a cause in fact of the January 7, 2014
11 event and subsequent injuries. *Viner v. Sweet*, 30 Cal. 4th 1232, 1234 & n.1 (2003). "In
12 a medical malpractice action, the evidence must be sufficient to allow the [trier of fact] to
13 infer that in the absence of the defendant's negligence, there was a reasonable medical
14 probability the plaintiff would have obtained a better result." *Alef*, 5 Cal. App. 4th at
15 216. Causation in a personal injury action must be proven within a reasonable medical
16 probability based upon competent expert testimony. *See Jones v. Ortho Pharm. Corp.*,
17 163 Cal. App. 3d 396, 402 (1985). "Mere possibility alone is insufficient to establish a
18 prima facie case." *Id.* "A possible cause only becomes probable when, in the absence of
19 other reasonable causal explanations, it becomes more likely than not that the injury was
20 a result of its action." *Id.*

21 **1. Plaintiff's Case in Chief**

22 Throughout this case, Plaintiff has presented a theory of causation that is
23 predicated on the consistency between the adverse side effects of rivastigime, the
24 medicine in the Exelon Patch, and Flores' January 7, 2014 symptoms. In Plaintiff's trial
25 brief, filed May 30, 2017, Plaintiff stated that Roman's failure to remove the prior Exelon
26 Patch caused Flores "to suffer the effects of 'overdose' that [are] specifically listed as
27 side effects in the pamphlet provided with the medication." Dkt. No. 36 at 1-2. Plaintiff
28 added that the "evidence will clearly show that . . . the effects suffered by Ms. Flores

1 were consistent with an overdose of the Exelon Patch.” *Id.* at 5. Likewise, in her
2 opening, Plaintiff emphasized that Flores exhibited symptoms that are known to be
3 adverse side effects of the Exelon Patch, including nausea and extreme vomiting.
4 Plaintiff added that Dr. Shannon Johnson, an expert in pharmacology, would testify to a
5 reasonable degree of medical certainty that the symptoms Flores suffered were consistent
6 with an overdose of the Exelon Patch.

7 As anticipated by Plaintiff’s opening, Dr. Johnson opined that the extra dose of
8 Exelon caused Flores to suffer from cholinergic toxicity. Dr. Johnson stated in his expert
9 report that acetylcholine accumulation can hyperstimulate nicotinic and muscarinic (that
10 is, the cholinergic, parasympathetic nervous system) receptors. He goes on to state that at
11 “higher (toxic) doses,” hyperstimulation of those receptors can lead to side effects which
12 include salivation, lacrimation, urination, defecation, and gastrointestinal problems,
13 among other effects. Dr. Johnson’s report also points out that section 10 of the
14 rivastigmine package insert from February 2015 states that “overdosage with
15 cholinesterase inhibitors can result in cholinergic crisis characterized by severe nausea,
16 vomiting, salivation, sweating, bradycardia, hypotension, respiratory depression, and
17 convulsions.” Dr. Johnson went on to quote the insert as stating that “Additional
18 symptoms associated with rivastigmine overdose are diarrhea, abdominal pain, dizziness,
19 tremor, headache, somnolence, confusional state, hyperhidrosis, hypertension,
20 hallucinations and malaise.”⁴

21 According to Dr. Johnson, Flores’ symptoms, as presented by the nursing staff at
22 SYHC, were consistent with an overdose of the Exelon Patch. Dr. Johnson testified that
23 the first symptom was vomiting, which was preceded by nausea. The second symptom
24 was agitation. Another symptom was emesis. According to Dr. Johnson, these
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27 ⁴ The Exelon insert in evidence, from February 2013, repeats verbatim the former quote from the Exelon
28 Patch insert but does not include the latter quote discussing “additional symptoms.” See Joint Exhibit
24-001.

1 symptoms then led to bradycardia, which is a symptom of cholinergic toxicity and
2 consistent with the Exelon Patch insert, and pulseless electrical activity. In his expert
3 report, Dr. Johnson states that the nausea, agitation, and emesis were symptoms of
4 cholinergic excess and that the pulseless electrical activity and bradycardia were
5 symptoms of cholinergic crisis. He further testified that passing out can also be a
6 symptom of an overdose of the Exelon Patch.

7 Plaintiff's nursing expert, Daniel Marinelli, also testified as to causation, over
8 objection from the Government.⁵ Marinelli testified that the acts and omissions of the
9 nursing staff at SYHC substantially contributed to the sequence of events which resulted
10 in Flores aspirating, developing pulseless electrical activity, which required intubation,
11 resuscitation, and emergency transfer to Sharp Chula Vista Medical Center. Marinelli
12 further opined that the acts and omissions of SYHC staff led Flores to overdose on the
13 Exelon Patch. Marinelli testified that the nausea and vomiting that Flores experienced,
14 which started the whole sequence of events leading to her hospitalization, is the most
15 common side effect of the Exelon Patch and of an Exelon overdose. Accordingly,
16 Marinelli opined that given the sequence of events and the fact that Flores had two
17 patches on her person that morning, her subsequent injuries should be attributed to the
18 medicine that was given in the wrong amount. Marinelli also testified that the Exelon
19 overdosage was the most likely culprit of the nausea and vomiting that Flores
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23 ⁵ The Government objected to Marinelli's causation testimony as beyond the scope of his expertise and
24 as cumulative of Dr. Johnson's testimony. The Court overruled the cumulative objection, but sustained
25 the Government's objection to Marinelli's opinions about the permanent increase in Flores' morbidity
26 and decrease in her quality of life as beyond the scope of his expertise. The Court did not, however,
27 prevent Marinelli from testifying as to his opinion that the acts and omissions of the SYHC nursing staff
28 caused Flores' hospitalization. The Court stated that it was inclined to allow Marinelli to testify about
how the acts and omissions of January 7, 2017 led to the need for intubation, but would decide opinion
by opinion, question by question, whether Marinelli's causation testimony was beyond the scope of his
expertise.

1 experienced on January 7, 2014, given that she did not overdose on any other medication
2 that day and had not experienced nausea and vomiting before.

3 **2. Defense Experts**

4 After Plaintiff finished the case in chief, the Government called two experts who
5 opined on the etiology of Flores' cardiac arrest and resulting hospitalization: Dr. Richard
6 Clark Jr., an expert in toxicology, and Dr. Denise Barnard, an expert in cardiology.

7 Dr. Clark opined that, based upon the progression of Flores' symptoms and the
8 treatment required to stabilize her, she was not suffering from a toxic overdose of Exelon
9 that was severe enough to directly cause bradycardia or loss of consciousness. In
10 reaching this conclusion, Dr. Clark testified that the resolution of Flores' symptoms was
11 the most important factor indicating against a toxic overdose of rivastigmine.

12 Dr. Clark testified that Flores' loss of consciousness and heart-related symptoms
13 were not the result of an Exelon overdose. Dr. Clark explained that rivastigmine directly
14 affects the nerve that can lower the heart rate and shut it down. As such, Dr. Clark stated,
15 an individual suffering from an Exelon overdose would not improve simply by receiving
16 oxygen. Here, Flores' condition improved as soon as the paramedics intubated her. Her
17 heart rate went from 30 bpm to 132 bpm in a matter of minutes. Dr. Clark emphasized
18 that an individual suffering from an Exelon overdose would not have responded to the
19 paramedics' course of treatment as did Flores because the drug would have had a
20 continued and direct effect on the heart. Dr. Clark added that an individual suffering
21 from an overdose of rivastigmine severe enough to directly cause cardiac arrest and
22 severe bradycardia would have needed atropine to reverse the symptoms. Atropine, Dr.
23 Clark explained, is the antidote and a life-saving therapy for individuals sick from
24 medications like the Exelon Patch. Accordingly, Dr. Clark opined that it was not
25 medically probable that an Exelon overdose caused Flores to lose her consciousness (i.e.,
26 the fainting or syncopal event) or become bradycardiac, leading to cardiac arrest.

27 The Court credits Dr. Clark's testimony as ruling out the possibility that the
28 placement of the two Exelon Patches directly caused Flores' loss of consciousness,

1 bradycardia, and cardiac arrest, notwithstanding Dr. Johnson's testimony. Dr. Johnson, a
2 pharmacologist, stated that Flores' symptoms, including the bradycardia, PEA, and loss
3 of consciousness, were "consistent with" an overdose of Exelon. He rendered this
4 opinion based on his understanding of the symptoms of a rivastigmine overdosage and
5 his reading of the side effects of an "overdosage" as stated in the Exelon package insert.
6 Dr. Johnson is not, however, qualified to diagnose patients for toxic events following
7 excessive drug dosage and he cannot authorize plans of care for individuals in such
8 situations. The opinion Dr. Johnson offered, moreover, was limited to whether Flores'
9 symptoms were "consistent with" an overdose of the Exelon Patch, not whether, based
10 upon clinical findings, the Exelon Patch actually caused all or some of Flores' symptoms.
11 Accordingly and given that Dr. Johnson is not qualified to diagnose an individual as
12 having suffered from a toxic overdose and that his opinion was limited to Flores'
13 symptoms rather than the course of her treatment and resolution of her symptoms, the
14 Court credits Dr. Clark's expertise as a toxicologist.

15 The Court finds, therefore, that Dr. Clark's testimony undermines Plaintiff's theory
16 of causation. Plaintiff stated, in her trial brief, that the Exelon Patch caused Flores to
17 suffer the side effects of "overdosage." Dr. Johnson explained that side effects of
18 "overdosage," as stated in the Exelon Patch insert, include severe nausea, vomiting,
19 salivating, sweating, and bradycardia, among other adverse effects. Dr. Johnson went on
20 to opine that Flores specifically exhibited the following symptoms of an Exelon
21 overdose: vomiting, preceded by nausea, agitation, emesis, bradycardia and pulseless
22 electrical activity. Dr. Johnson explained that the former three symptoms were the result
23 of cholinergic excess caused by the Exelon Patch and that the latter two were the result of
24 cholinergic crisis induced by the Exelon Patch. Dr. Clark's testimony, however, belies
25 Dr. Johnson's opinion that the heart-related symptoms that Flores exhibited on January 7,
26 2014 were side effects of the Exelon Patch. Stated differently, Dr. Clark's expert opinion
27 made clear that the Exelon Patch did not directly cause Flores to lose consciousness or to
28 suffer from bradycardia and PEA. While those symptoms may have been "consistent"

1 with an overdose, as Dr. Johnson explained, Dr. Clark opined that the resolution of
2 Flores' symptoms made it medically improbable that an overdose of the Exelon Patch
3 had actually caused those symptoms.

4 **3. "Domino" Theory of Causation**

5 During the cross-examination of Dr. Clark, Plaintiff elicited testimony that
6 appeared to be directed at a new theory of causation grounded in a kind of "domino"
7 effect. The "domino" theory of causation, unlike Plaintiff's "overdose" theory of
8 causation, focused on whether the Exelon Patch initiated the sequence of events that led
9 to Flores' hospitalization rather than whether the Exelon Patch directly caused Flores'
10 most serious symptoms (i.e., bradycardia and PEA), which had required hospitalization.

11 Plaintiff never mentioned a "domino" theory of causation in her trial brief or
12 opening statement. Neither of Plaintiff's experts competently testified to such a theory at
13 trial or in their expert reports. Rather, the "domino" theory appeared exclusively in
14 Plaintiff's cross-examination of Defendant's experts and in her closing argument. During
15 her closing, Plaintiff stated that a kind of domino effect connected Defendant's
16 negligence to Flores' hospitalization. First, Defendant's negligent misapplication of the
17 Exelon Patch caused Flores to become nauseous and vomit. Next, Flores fell out of her
18 chair. Then, Flores lost the ability to breathe because she was left on her back on the
19 floor. From there, Flores became pulseless to the point where she required CPR and
20 intubation.⁶

21 This newly-developed "domino" theory of causation, however, cannot sustain
22 Plaintiff's burden on causation.

26 ⁶ The Court observes that while Plaintiff appeared to be offering a new "domino" theory of causation in
27 her closing, Plaintiff did not abandon the "overdose" theory of causation. In rebuttal to the
28 Government's closing argument, Plaintiff argued that Dr. Johnson had carried Plaintiff's burden as to
causation when he testified that Flores' symptoms and condition were consistent with an overdose of the
Exelon Patch.

1 For one, Plaintiff's 11th-hour theory raises serious concerns about the fairness of
2 the proceeding. As the Government pointed out in its closing argument, it did not have
3 notice of Plaintiff's "domino" theory of causation until Plaintiff developed it on cross-
4 examination. Courts have observed that newly-introduced legal theories that prejudice
5 the opposing party may be properly excluded. *See Pac. Enters. v. Fed. Ins. Co.*, 189 Fed.
6 App'x 591, 592 (9th Cir. 2006) (exclusion of expert's theory of loss, as presented at trial,
7 not required because "expert did not present a new theory which prejudiced or harmed"
8 opposing party); *France Telecom S.A. v. Marvell Semiconductor Inc.*, 82 F. Supp. 2d 987,
9 1007 (N.D. Cal. 2015) (finding that non-infringement theory presented at trial was not
10 "new" and therefore "did not warrant rebuttal"). Here, the Government was prejudiced
11 by Plaintiff's new theory of causation because it was deprived of the opportunity to
12 prepare witnesses and evidence to rebut Plaintiff's alternative theory. *See Scott & Fetzer*
13 *Co. v. Dile*, 643 F.2d 670, 673 (9th Cir. 1981) (district court denied party right to prepare
14 effective cross-examination, present rebuttal witnesses and exhibits when it permitted
15 opposing party to call witnesses whose identity and exhibits were not disclosed until after
16 trial began).

17 Two and relatedly, Plaintiff's reliance on any opinions that she elicited during
18 cross-examination raises concerns under Fed. R. Civ. P. 26 and 37. Rule 26 states that
19 expert witnesses must disclose "all opinions the witness will express and the basis and
20 reasons for them" along with "the facts or data considered by the witness in forming
21 them" before trial. Fed. R. Civ. P. 26(a)(2)(B)(i)-(ii). Rule 37, in turn, prevents a party
22 from using information or witnesses not identified as required by Rule 26(a) "to supply
23 evidence on a motion, at a hearing, or at a trial, unless the failure was substantially
24 justified or is harmless." Fed. R. Civ. P. 37(c)(1); *Yeti by Molly Ltd. v. Deckers Outdoor*
25 *Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001) ("exclusion is an appropriate remedy for
26 failing to fulfill the required disclosure requirements" under Rule 37(c)(1)). As stated
27 below, however, no competent expert offered an opinion predicated on this "domino"
28 theory of causation in their Rule 26 report.

1 Three and even if it is proper for the Court to consider Plaintiff's "domino" theory
2 of causation and the evidence supporting it, the theory still fails because it has not been
3 proven within a reasonable medical probability based upon competent expert testimony.
4 *See Jones*, 163 Cal. App. 3d at 402.

5 Plaintiff's case in chief offers no support for Plaintiff's "domino" theory of
6 causation. Plaintiff stated in closing that the extra dose of Exelon caused Flores to
7 become nauseous and vomit; that she then fell out of her chair; that she lost the ability to
8 breathe because she was left on her back on the floor; and that from there she became
9 pulseless. Gonzalez's testimony, however, belies this chain of events because Gonzalez
10 testified that she could no longer pick up Flores' pulse while Flores was still seated in her
11 chair. Plaintiff's expert, moreover, did not opine on any "domino" theory of causation.
12 Dr. Johnson's expert opinion was that the Exelon Patch directly caused Flores'
13 bradycardia and PEA, not that it initiated a chain of side effects that led to bradycardia
14 and cardiac arrest. Accordingly, Dr. Johnson's testimony does not advance Plaintiff's
15 "domino" theory of causation.

16 Marinelli's testimony also does little, if anything, to advance Plaintiff's "domino"
17 theory of causation. At trial, Marinelli opined that Defendant's acts and omissions
18 substantially contributed to the sequence of events that led to Plaintiff aspirating,
19 developing pulseless electrical activity, which required intubation, resuscitation, and
20 emergency transfer to the Sharp Chula Vista Medical Center. He testified that
21 Defendant's acts and omissions led Flores to overdose on the Exelon Patch.

22 The Court, however, agrees with the Government's objection that Marinelli is not
23 qualified to offer an opinion on medical causation. *See, e.g., Jerden v. Amsutz*, 430 F.3d
24 1231, 1239-40 (9th Cir. 2005) (in diversity medical malpractice case, court precluded
25 nurse from offering opinion about observations of an MRI); *Earp v. Cnty. of Tulare*, 2012
26 WL 1076217, *4 (E.D. Cal. Mar. 29, 2012) (nurse prohibited from testifying as to
27 whether denial of medical care caused worsening infection because nurses "not
28 competent to opine on the medical causation issues"). Moreover and even if Marinelli's

1 testimony was entitled to some weight, his opinions were too general and speculative to
2 support Plaintiff's "domino" theory of causation.⁷

3 The Defendant's expert testimony is also not enough to sustain Plaintiff's
4 "domino" theory of causation to a reasonable degree of medical certainty. In closing,
5 Plaintiff argues that Dr. Clark admitted causation. Plaintiff is mistaken. Dr. Clark never
6 rendered a medical opinion that the Exelon Patch caused adverse side effects that spiraled
7 into Flores' cardiac arrest to a reasonable degree of medical certainty.⁸ In fact, Dr. Clark
8 specifically opined that it was not medically probable that the Exelon Patch caused
9 Flores' nausea and vomiting, that it caused aspiration, that it caused bradycardia, or that it
10 caused loss of consciousness.

11 Dr. Barnard, similarly, did not opine, to a reasonable degree of medical certainty,
12 that the Exelon Patch caused the adverse side effects that led to Flores' cardiac arrest.⁹

14
15 ⁷ At one point, Marinelli testified that the sequence of events that unfolded on January 7, 2014 should be
16 attributed to the Exelon Patch because it was the medicine given in the wrong amount. Such an opinion,
17 is overly deductive, not grounded in medical fact, and not specific enough to offer any reasonable
18 medical probability on causation.

19 ⁸ Q: But if she is vomiting and she is aspirating, sucking the vomit in, that prevents one from breathing,
20 correct?

21 A: It doesn't prevent one from breathing, but it prevents one from getting, potentially, oxygen into their
22 blood.

23 Q: If one is unable to get oxygen in the blood, they lose consciousness?

24 A. They can.

25 Q: It's like a domino effect?

26 A: Correct.

27 Q: The domino effect began when she developed nausea and led to vomiting, and led to the inability to
28 breathe, which led to the PEA, which led the possible cardiac arrest, correct?

A: Correct

Dr. Richard Clark Trial Transcript, Dkt. No. 49 at 67:23 – 68:10.

⁹ Q: And so you will agree it was kind of a domino effect? We have the Exelon Patch given; we have her
suffering nausea, vomiting, her collapsing; and she could have had a second vasovagal event after that,
correct?

A: Correct.

1 Dr. Barnard testified that, within all reasonable medical probability, Barnard suffered
2 from a severe vasovagal episode, which led to her hospitalization. She did not, however,
3 testify to a reasonable degree of medical certainty that the side effects of the Exelon
4 Patch caused that vasovagal event.¹⁰ In fact, Dr. Barnard emphasized that mental
5 symptoms, like agitation, as well as physical symptoms, like nausea or vomiting, can
6 trigger a vasovagal event and that there was evidence in the record to suggest that Flores
7 had signs of both mental and physical stress on January 7, 2014.

8 To conclude, Plaintiff's belated and under-developed "domino" theory of causation
9 cannot sustain her burden on causation. Dr. Clark undermined Plaintiff's theory of
10 causation when he testified to a reasonable degree of medical probability that the two
11 doses of the Exelon Patch did not cause Flores to suffer from the heart-related symptoms
12 that led to her hospitalization. In response to such unfavorable testimony, Plaintiff
13 attempted to save her case by introducing a new theory of causation, the "domino"
14 theory, after her case in chief had closed. This theory, however and irrespective of
15 whether it was timely raised, is not fully-developed and is not supported by any
16 competent expert testimony to a reasonable degree of medical certainty. The Court
17 cannot conclude that Plaintiff has demonstrated by a preponderance of the evidence that
18 the Exelon Patch caused Plaintiff's injuries by initiating a "domino" effect, when Plaintiff
19 has not even made clear what facts make up that chain of events and when no expert has

20
21 Q: And all of that is consistent with the use of the Exelon Patch, correct?

22 A: It's on the list of potential side effects.

23 Dr. Denise Barnard Trial Transcript, Dkt. No. 50 at 40:10-17.

24 ¹⁰ Q: But let's focus on January 7, 2014. Assuming there's time for the medication to take effect,
25 assuming that the medication caused her to suffer from nausea and vomiting, and assume that she was
26 suffering from some type of fear, to a reasonable degree of medical probability, that would be consistent
27 with the use of the Exelon Patch, correct?

28 A: With three theoreticals in there, sure.

Dr. Denise Barnard Trial Transcript, Dkt. No. 50 at 41:15-21.

1 opined that the Exelon Patch caused, to a reasonable degree of medical probability, that
2 chain of events to occur. Accordingly, the Court finds that Plaintiff's alternative
3 "domino" theory of causation fails under California law. *See Jones*, 163 Cal. App. 3d at
4 402 (causation in a personal injury action must be proven within a reasonable medical
5 probability based upon competent expert testimony).

6 **D. Damages**

7 Even if Plaintiff had carried her burden as to causation, the Court notes that it
8 would have, nonetheless, limited any damages flowing from SYHC's breach to those
9 costs relating to Flores' hospitalization and any pain and suffering endured as a result.
10 The Court would have limited damages in this way because the record and testimony
11 before the Court does not demonstrate that Flores suffered any long-term effects from the
12 January 7, 2014 incident.

13 Plaintiff stated in her trial brief, for instance, that SYHC's negligence caused her
14 Alzheimer's to progress in a matter of hours to a stage that it otherwise would have taken
15 years to reach. Dkt. No. 36 at 10. This proffer, however, was unsupported by competent
16 expert testimony and completely undermined by the testimony of Dr. Lobatz, the only
17 neurologist to testify. Dr. Lobatz opined that the events of January 7, 2014, and Flores'
18 subsequent hospitalization through January 9, 2014, had no effect on the underlying
19 neurological progression of her Alzheimer's disease. According to Dr. Lobatz,
20 Alzheimer's disease will progress no matter what is done, positive or negative. He
21 further testified that Flores' condition in May 2016 was not much different than what he
22 would have expected given the severity of her Alzheimer's in September 2013 and given
23 that her trajectory began in 2008. As such, Plaintiff has failed to prove that the January 7,
24 2014 hospitalization worsened her Alzheimer's.

25 Plaintiff also stated in her trial brief that her quality of life was "destroyed" and
26 otherwise adversely affected by the January 7, 2014 incident. Yet again, however,
27 Plaintiff's case in chief failed to adequately support this assertion. Plaintiff offered no
28 competent expert testimony demonstrating the effect of the January 7, 2014

1 hospitalization on the quality of her life.¹¹ Instead, Plaintiff's case relied on Flores'
2 daughters' testimony to detail how Flores was altered by the hospitalization. The
3 daughters' testimony, however, is undermined by Dr. Lobatz' expert testimony. At trial,
4 Dr. Lobatz emphasized that his expert opinion was based on the fact that Flores' primary
5 care physician had observed that Flores was at her baseline level after the incident.
6 Indeed, as the medical records in evidence themselves demonstrate, Dr. Shachar
7 evaluated Flores ten days after the incident, on January 17, 2014, and specifically noted
8 that Flores was "back to baseline." Joint Exhibit 16-187. That Flores' own primary care
9 physician observed that Flores was unchanged by the January 7, 2014 incident severely
10 undermines the Plaintiff's case on damages.

11 Finally, there is also insufficient evidence before the Court to conclude that the
12 January 7, 2014 hospitalization had any effect on Flores' long-term cardiology prognosis.
13 Dr. Barnard opined that there was essentially a zero percent chance that Flores had a
14 heart attack on January 7, 2014. Dr. Barnard reviewed the results of an EKG
15 (echocardiogram) test that measured Flores' heart muscle, heart valves, heart function,
16 and heart filling. Upon review of that result. Dr. Barnard concluded that there was really
17 no change in Flores' cardiac conduction and cardiac function by the time she was
18 released. Dr. Barnard further testified that the EKG did not show damage to the heart
19 muscle. Accordingly, Plaintiff has also failed to prove that Flores suffered any long-term
20 heart damage from the January 7, 2014 incident.

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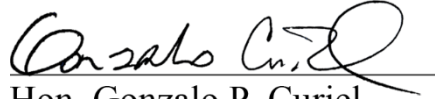
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27 ¹¹ As stated previously, the Court sustained the Government's objection to Marinelli's expert opinion
28 insofar as he asserted that SYHC's deviations from the standard of care put Flores' life in danger and
resulted in a permanent increase in her morbidity and decrease in her quality of life.

1 **CONCLUSION**

2 Based upon its findings of fact, conclusion of law, and based on the foregoing
3 analysis, the Court enters judgment in favor of Defendant and against Plaintiff.

4 **IT IS SO ORDERED.**

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6 Dated: June 30, 2017

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8 Hon. Gonzalo P. Curiel
9 United States District Judge
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